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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,748	06/15/2001	Steven M. Ruben	PF523P1	5654

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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/880,748	RUBEN ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-96* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The art unit designated for this application has changed. Applicants(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-74 and 80-86, drawn to an antibody that immunospecifically binds to BlyS and a kit comprising of the said antibody, classified in class 530, subclass 387.1. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized 8 species sets (A-H); election of a species from each set is required is required.

II. Claims 75-78, drawn to an isolated nucleic acid molecule encoding an antibody, a vector and host cell, classified in classes 536 and subclass 23.1 and class 435, subclasses 320.1, 325 and 252.3. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized 8 species sets (A-H); election of a species from each set is required is required.

III. Claim 79, drawn to a cell line engineered to express an antibody, classified in class435, subclass 325. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the

below summarized 8 species sets (A-H); election of a species from each set is required is required.

IV. Claim 87, drawn to a method for detecting aberrant expression of BlyS protein, classified in 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized 8 species sets (A-H); election of a species from each set is required is required.

V. Claim 88, drawn to a method for diagnosing a disease or disorder associated with aberrant BlyS expression or activity, classified in class 436, subclass 64. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized 9 species sets (A-I); election of a species from each set is required is required.

VI. Claims 89-96, drawn to a method of treating, preventing or ameliorating a disease associated with aberrant BlyS, classified in class 514, subclass 2. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized 9 species sets (A-I); election of a species from each set is required is required.

Sequence Election Requirement Applicable to All Groups:

3. In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group draw to amino acid/polypeptide sequence, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic sequence (See MPEP § 803.04). It is noted that the multiple of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic sequences effectively impossible to reasonably implement.

MPEP § 803.04 states:

Nucleotides sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction and not a specie election requirement.

SPECIE ELECTION REQUIREMENT

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

SPECIES A (For all Groups)

5. Species of single chain antibody molecules ("scFvs") are cited in Table 1 of the specification, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to elect an unspecified type of "scFvs" or a "scFvs" from those listed Table 1 in this instant specification. It is noted that these "scFvs" types are utilized in all groups although only cited specifically in Group I. Applicants are also required to define the correspondence of this elected specie to the above elected sequence.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 36, 43-84, and 87-96 are generic in their respective groups. These species are distinct due to the use and intended goal of each species. Each specific domain represented by specific scFvs of a specific SEQ ID NO is uniquely recognized by the second antibody. Therefore, this causes each binding site to be specifically recognized by a secondary antibody that is made to specifically recognize the antigen that was used to raise the antibody. The uniqueness of each second antibody could be used to distinguish one antigen from the other. Therefore, the different use and intended goal of each species cause the species to be distinct.

SPECIES B (For all Groups)

7. Species of various antibodies are cited in claims 48, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to elect an unspecified type of antibody or a type of antibody from those listed in claims 48.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-96 are generic in their respective groups.

SPECIES C (For all Groups)

8. Species of antibodies comprising distinct heavy chain immunoglobin constant domains are cited in claims 49, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to elect an unspecified type of antibody or a type of antibody from those listed in claims 49.

9. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-96 are generic in their respective groups.

SPECIES D (For all Groups)

10. Species of antibodies comprising distinct heavy chain immunoglobin constant domains are cited in claims 50, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to elect an unspecified type of antibody or a type of antibody from those listed in claims 50.

11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-96 are generic in their respective groups.

SPECIES E (For all Groups)

12. Species of antibodies that specific dissociation constant (Kd) are cited in claims 51, which are generally separately analyzed and published, and thus document the undue search

burden if searched together. Thus, applicants are required to elect an unspecified type of antibody or a type of antibody from those listed in claims 51.

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-96 are generic in their respective groups.

SPECIES F (For all Groups)

14. Species of antibodies wherein distinct therapeutic or cytotoxic agents are cited in claims 58, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to elect an unspecified type of antibody or a type of antibody from those listed in claims 58.

15. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-96 are generic in their respective groups.

SPECIES G (For all Groups)

16. Species of antibodies wherein the receptors are cited in claims 61 and 62, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to elect an unspecified type of antibody or a type of antibody from those listed in claims 61 and 62.

17. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-60 and 63-96 are generic in their respective groups.

SPECIES H (For all Groups)

18. Species of second antibodies that reduce the binding of the antibody of claim 1 by a specific range are cited in claims 84, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to elect an unspecified type of antibody or a type of antibody from those listed in claims 84.

19. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-96 are generic in their respective groups.

SPECIES I (For Groups V and VI)

20. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species IA: Unspecified disease.

Species IB: Systemic Lupus Erythematosus.

Species IC: Rheumatoid Arthritis.

Species ID: Common Variable Immunodeficiency (CVID).

Species IE: AIDS.

21. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 88-92 are generic in their respective groups. These species are distinct because they are specific diseases. Therefore, each would require a specific treatment regiments which are generally separately analyzed and published, and thus document the undue search burden if searched together.

22. Applicant is advised that a reply to this requirement must include an identification of a specie from list of specie sets cited above that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

23. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

24. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

25. Inventions in Groups [I, IV, V, VI], II, and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the nucleic acid of Group II may be utilized in the distinct usages as an antibody in Groups I, IV, V, VI, which is an antibody

encoded by the nucleic acid of Group II. As in Group III, which is a cell line engineered to express the antibody encoded by the said nucleic acid. Alternatively, a polynucleotide molecule could be used to generate an antisense oligonucleotide for RNA interference studies, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

26. Inventions in Groups I, IV, V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the antibody of Group I, may be utilized in the distinct usages as needed in Group IV, which is a method for detecting aberrant expression of BlyS protein. As needed in Group V, which is a method for diagnosing a disease or disorder associated with aberrant BlyS expression or activity. As need in Group VI, which is a method for treating, preventing, or ameliorating a disease associated with aberrant BlyS. Alternatively, an antibody could be used to protein localization studies, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

27. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

28. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

29. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

30. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

33. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
April 30, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER